EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Internal Quality Assurance Audits

SOP QA-02-02

Date Revised: 08-28-02

Prepared By: _____Date:___/___/___

Print Name:_____
Quality Assurance Officer

Reviewed By:_____ Date: ___/___/___

Print Name:_____
Laboratory Director

_____ Date: ___/___/___

Print Name:_____
OPP Quality Assurance Manager

Date Issued: _____/_____/_____

Withdrawn By: _____ Date: ____/_____/____

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 The purpose of this SOP is to describe the procedure for the scheduling, preparation, performance, and reporting of the internal audits conducted at the OPP Microbiology Laboratory.

1.2 This SOP applies to internal audits conducted of the general operations of the Laboratory, performance of specific efficacy testing methods, and other data generated under unique project plans. The purpose of the audits is to validate the quality of laboratory operations by examining systems and procedures, the adequacy of documentation of those systems and procedures, and the level of consistency between the written documentation and actual laboratory practices. The audits are meant to comply to the requirements of the EPA Good Laboratory Practice (GLP) Standards for inspections to ensure the integrity of study data.

1.3 The designated OPP Microbiology Laboratory Quality Assurance Officer (QAO) has the responsibility for operation of the Quality Assurance Unit (QAU) for the Laboratory, including responsibility for conducting audits.

2.0 DEFINITIONS:

2.1 QAO = Quality Assurance Officer, Office of Pesticide Programs (OPP), Biological and Economic Analysis Division (BEAD), Antimicrobials and Plant Pathogens Branch (APPB).

2.2 QAU = Quality Assurance Unit, Office of Pesticide Programs (OPP), Biological and Economic Analysis Division (BEAD), Antimicrobials and Plant Pathogens Branch (APPB).

2.3 QAM = Quality Assurance Manager, Office of Pesticide Programs (OPP)

2.4 Laboratory = OPP Microbiology Laboratory located in the Environmental Science Center, Fort Meade, Maryland.

2.5 Team Leader = The team leader for the group of OPP analysts located at the Laboratory.

2.6 Laboratory Director = Branch Chief, Antimicrobials and Plant Pathogens

Branch (APPB).

2.7 GLP = Good Laboratory Practices (EPA GLPLs are codified in 40CFR Part 160).

3.0 HEALTH AND SAFETY:

3.1 Health and safety requirements described in SOP MB-01, Lab Biosafety, will be followed during on-site audits of the methods and laboratory operations.

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 The Quality Assurance Officer is responsible for completing the Agency's basic quality assurance course "Introduction to EPA Quality Systems." Continuing education is recommended by participating in the EPA Annual National QA Conference on Managing Environmental Quality Systems and by attending additional workshops or courses offered by the EPA Office of Environmental Information Quality Staff or other organizations that may offer such training.

7.0 APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Summary:

The QAO and the Laboratory Team Leader shall prepare an annual list of the internal systems audits to be performed during that calendar year at the Laboratory. The list will include technical audits of general laboratory functions. The list will also include the test methods conducted by the

laboratory. The proposed list will be subject to modification from the samples collected, actual tests conducted, and other factors affecting laboratory scheduling. All audits will use laboratory SOPs and/or protocols as the audit standard. In addition, for the audit of general laboratory functions, a checklist will be used for guidance (see 16.1). After the audit is complete, the QAO shall issue an audit report documenting observations/findings and conclusions/recommendations. The Team Leader will then submit corrective action plans for approval by the QAO in response to the audit report. Implementation of corrective action plans will be according to sections 10.2.3.9 and 10.2.4.1. When corrective actions have been completed, the QAO will prepare a close-out memorandum indicating that no more action is necessary. In addition to these periodic audits, the QAU will conduct an audit of every test conducted in the laboratory which involves the collection of environmental data.

10.2 Operation:

10.2.1 The QAO and the Team Leader shall prepare a list of systems audits and general method audits each year. The list will reflect all audits of laboratory operations and methods to be performed during the year, using the master testing schedule, project plans, and other factors as a guide.

10.2.1.1 The annual technical audit of general laboratory operations will include a review of the systems in place for quality assurance, sample handling, preparation, analysis and data reduction. Adherence to guidelines and procedures stipulated in laboratory quality control, equipment calibration and maintenance, test method, and chain of custody SOPs will be audited during these reviews.

10.2.1.2 Specific test methods employed by the laboratory will be audited at the beginning of their use and every year thereafter in which the methods are performed.

10.2.1.3 The QAM and the Laboratory Director shall be informed of the audit schedule.

10.2.1.4 The annual technical audit of general laboratory operations will be based on checklists of current versions SOPs followed in the Laboratory.

10.2.1.5 The audit of each test method or protocol will be based on the individual test methods. The laboratory's SOPs for these test methods will be the documents consulted during these audits. Apparatus and supplies will be reviewed for conformance to SOP specifications. A sampling of calculations will be verified and documentation will be examined for accuracy and completeness.

10.2.2 Audit Performance

10.2.2.1 The annual technical audit of general laboratory operations will include a review of the systems in place for quality assurance, sample handling, preparation, analysis and data reduction.

10.2.2.2 The QAO has responsibility for on-site audits at the Laboratory. The QAO, may designate that certain audits be performed by other qualified QA/QC trained individuals, such as a contractor.

10.2.2.3 At the initiation of an announced audit, the Team Leader shall be contacted and the audit purpose reviewed. The lead analyst will provide any necessary assistance, such as making personnel available, locating records, etc. Unannounced audits may also be conducted.

10.2.2.4 SOPs will be used as the audit standard against which operations and procedures will be

evaluated. A checklist will also be used as guidance during the audit of general laboratory operations (see 16.1). The QAO may probe related areas in depth, as necessary, to satisfy the objective of the audit.

10.2.2.5 During the audit, if applicable, previous corrective action plans shall be verified.

10.2.2.6 At the completion of the audit, all observations and findings shall be reported to the Team Leader and analyst(s) responsible for resolving the findings and initiating correction action.

10.2.3 Audit Reporting

Audit reports will be formatted and processed as described below.

10.2.3.1 Audit Identification

An audit report shall be identified with the following information:

Audit Title _____

Audit Number _____

Audit Date _____

Performed by _____

The audit number will consist of the letters OPP-MICRO followed by the two digits of the fiscal year and the sequential number of the audit performed that year. For example, the first audit performed in the lab in Calendar Year 2000 would be coded OPP-MICRO 00-01.

10.2.3.2 Objective - Short paragraph(s) that outlines the objectives of the audit.

10.2.3.3 Scope - A brief description of when the audit was performed, what areas were reviewed and the names of key persons contacted.

10.2.3.4 Findings/Observations - Each finding or observation is listed. When used, a completed checklist shall be included.

10.2.3.5 Previous Audits Status - A short summary detailing the status of corrective action of previous audits.

10.2.3.6 Conclusions/Recommendations - An overall summary of the audit with recommendations for a time-frame for corrective action.

10.2.3.7 Checklists - Checklists that are used during the audit will be completed and attached to the report.

10.2.3.8 Signature(s) - Signature(s) of each person performing the audit.

10.2.3.9 Audit reports shall be issued within 30 working days of the conclusion of the audit.

10.2.3.10 Copies of audit reports shall be directed to the Laboratory Team Leader, the Laboratory Director, and the OPP QAM.

10.2.4 Audit Follow-up

10.2.4.1 Audit report responses shall be returned to the QAO and Laboratory Director within 30 working days from the date the audit report was issued, or a schedule for completion of corrective

actions must be prepared that would have all corrective actions scheduled to be completed within 60 working days of the date of the audit report. The Team Leader is responsible for addressing each finding or observation. A reason for the noncompliance, as well as a plan for corrective action, is required. If the QAO finds the plan of corrective action deficient, the QAO will discuss the situation with the Team Leader and the Laboratory Director. If unresolved issues remain, the QAO will raise them to the OPP QAM who will discuss them with the Team Leader and the Branch Chief.

11.0 DATA ANALYSIS/CALCULATIONS:

11.1 The data analysis and calculations included in the audit of selected protocols and associated data will be verified as part of the audit process.

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 An annual audit schedule shall be prepared and be filed with QAO.

12.2 An audit report shall be prepared for each audit.

12.3 The Team Leader will devise a corrective action plan addressing each audit finding.

12.4 A close-out memorandum will be prepared by the QAO indicating that no further follow-up is required.

12.5 Results of reviews of data and reports, findings from audits, audit responses, and other documentation associated with audit activities will be filed in the Quality Assurance Officer's files located in locked file cabinets in file room D217. These documents are subject to OPP's records retention schedule as specified in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL/QUALITY ASSURANCE:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Based on audit findings, corrective actions must be completed within 30 working days of the audit report, or a schedule for completion of corrective actions must be prepared that would have all corrective actions scheduled to be completed within 60 working days of the date of the audit report.

15.0 REFERENCES: None

16.0 FORMS AND DATA SHEETS

16.1 OPP Microbiology Laboratory Technical Systems Audit Checklist

OPP MICROBIOLOGY LABORATORY
TECHNICAL SYSTEMS AUDIT CHECKLIST

DATES: _____ **REPORT NO:** _____

AUDITORS: _____

_____

_____

SECTION I: QA MANAGEMENT SYSTEMS

1. Are staff familiar with the OPP Quality Management Plan?
2. Are staff familiar with GLP requirements?
3. Do staff understand the organizational structure of the EPA/OPP/Laboratory QA program?
4. Are communication channels defined for resolving QA/QC problems?
5. Are SOPs written for all routine procedures?
6. Are approved and current version of SOPs in use?
7. Are procedures in-place for managing SOPs? (filing, distribution, and version control)
8. Are clear communication channels in place for reporting QA/QC problems?
9. Is QA training available?
10. Does management support continuous quality improvement activities including training?

Comments:

SECTION II: PROJECT MANAGEMENT SYSTEMS

1. Does the laboratory have a schedule for sample collection?

2. Are the number of samples collected aligned with laboratory capacity?

3. Is the laboratory notified that samples have been shipped?

4. Does the laboratory have adequate in-house sample handling procedures?

5. Are testing schedules reasonable and achievable?

6. Are results reported on time?

7. Is sufficient coordination occurring between the laboratory and other involved EPA organizations?

8. Are supplies obtainable in a timely manner?

9. Does each disinfectant have its own project file?

10. Are data review and approval procedures clearly specified and followed?

Comments:

SECTION III: LABORATORY MANAGEMENT SYSTEMS

Personnel

1. Do personnel have appropriate academic training?

2. Have personnel received sufficient on the job training?

3. Do personnel receive appropriate medical monitoring?

4. Have personnel been trained on use of personal protective equipment (PPE), cleanup & disposal of chemical and biological hazards, and evacuation procedures?

Facilities

3. Has sufficient laboratory space been allocated?

4. Are laboratory areas maintained in a clean and organized manner?

5. Is sufficient lighting provided?

6. Is a safety plan available?

7. Are facilities properly sanitized?

8. If needed, are specialized laboratories available for working with microbial, chemical, and/or radiological hazards.

Equipment and Supplies

9. Are QC procedures adequate for the pH meter?

10. Are QC procedures for the autoclave adequate?

11. Are QC procedures for the refrigerators/freezers adequate?

12. Are QC procedures for the microscopes adequate?

13. Are QC procedures for the incubators adequate?

14. Are reagent grade or higher purity chemicals used to prepare standards?

15. Is the following information documented for all reagents/standards used?

    a. Manufacturer
    b. Date of receipt
    c. Date opened
    d. Lot number
    e. Expiration date

16. Does documentation exist for standards preparation that uniquely identifies the reagents/solvents used and the method of preparation?

17. Does documentation exist for identification of standard preparer and date of standard preparation?

18. Are calibration standards validated prior to use?

19. Are standards being replaced at the proper intervals?

20. Are manufacturer's maintenance manuals available?

21. Are maintenance logs kept for lab equipment/instrumentation?

22. Is service on equipment/instrumentation readily available?

23. Are replacement parts for equipment/instrumentation available?

24. Is the analytical balance located in an area free from drafts and rapid temperature changes?

25. Do balances and other calibrated equipment (BSCs, ...) have calibration stickers showing date of last certified calibration and date of next scheduled calibration?

26. Are records available for in-house calibration of balances?

27. Do micropipetters have logs indicating calibration checks performed in-house?

28. Do records exist for monitoring of laboratory water systems?

29. Are glassware cleaning procedures adequate?

30. Are temperature logs available for incubators, refrigerators, freezers, water baths?

31. Are sterilization procedures documented and sufficient?

32. Are media preparation procedures adequate?

Analytical Methods

33. Are appropriate controls being used?

34. Are verification tests being conducted?

Sample Collection/Handling

35. Does the lab have reference copies of SOPs describing correct collection of samples?

Comments:

SECTION IV: DATA MANAGEMENT SYSTEMS

1. Are data records legible?
2. Do data records indicate a date and responsible party?
3. Are changes to data records dated and initialed by the person who made them?
4. Can any data not stored in the product file be tracked?
5. Do the product files identify the relevant SOP(s) that were used for testing?
6. Have data manipulation procedures been adequately described?
7. Have calculations been verified?
8. Are data (electronic and hard copy) stored in an organized, secure, and retrievable fashion?
9. Are staff aware of Federal policies on records management?

Comments:

SECTION V: PROBLEM RESOLUTION

1. Has a person been designated to follow-up on previously identified problems?

2. Has a time frame been stipulated for resolving problems?

3. Does documentation of the resolution of problems exist?

Comments: